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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/800,306	03/12/2004	Michael D. Griffin	03-12896	1754
25189	7590 10/30/2006		EXAMINER	
CISLO & THOMAS, LLP			ANDERSEN, MICHAEL T	
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SANTA MONICA, CA 90401-1211			3734	<u> </u>
•			DATE MAILED: 10/30/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
Office Action Summary		10/800,306	GRIFFIN ET AL.			
		Examiner	Art Unit			
		M. Thomas Andersen	3734			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠	Responsive to communication(s) filed on 10 Au	uaust 2006.				
•	•	action is non-final.				
· —	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
,	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Dispositi	on of Claims		·			
4)⊠	4)⊠ Claim(s) <u>1,25-27,29-38 and 40-48</u> is/are pending in the application.					
•	4a) Of the above claim(s) is/are withdrawn from consideration.					
5)[Claim(s) is/are allowed.					
6)⊠	☐ Claim(s) 1,25-27,40-48 and 29-38,40-48 is/are rejected.					
7)						
8)□	Claim(s) are subject to restriction and/or election requirement.					
Applicati	on Papers					
9) ☐ The specification is objected to by the Examiner.						
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority u	ınder 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
	a) ☐ All b) ☐ Some * c) ☐ None of:					
•	1. Certified copies of the priority documents have been received.					
	2. Certified copies of the priority documents have been received in Application No					
	3. Copies of the certified copies of the priority documents have been received in this National Stage					
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
			•			
Attachmen	t(e)					
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date.						
3) 🔲 Inforr	mation Disclosure Statement(s) (PTO/SB/08)	5) Notice of Informal P 6) Other:	atent Application			
Fape S Patent and Ti	r No(s)/Mail Date	o) [] Otilet				

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DETAILED ACTION

Acknowledgement is made of the response filed 8/10/2006, to the non-final Office action dated 6/06/2006.

Specification

Acknowledgement is made of the previous amendment of the specification. The objection to the specification is thus withdrawn.

Claim Rejections - 35 USC § 112

The rejection to claim 38 under 35 USC § 112 is withdrawn.

Response to Amendments

Applicant's amendments filed 8/10/2006 have been fully considered. These amendments were discussed in an interview on 8/01/2006. At the interview the Herbert reference (US 5,868,771) was thoroughly discussed. Applicant argued that perhaps the most significant distinction between Herbert and Applicant's invention is that "[t]he bent distal end 302 [in Herbert] must be held in this position [i.e., urged against one sidewall of the protective sheath] to permit the sheath's diagonal base edge 206 formed there to 'encounter' it and 'prevent the blade from passing through the end of the sheath 200,' (Column 6, lines 6-8)." See Reply to Office Action dated 6 June 2006, page 15 of 17. The Examiner then and now agrees with such a distinction.

Thus, to distinguish the Herbert reference from Applicant's own invention,

Applicant has amended the independent claims by adding the limitation substantially as follows: "said housing being formed with at least one retaining member forming a hooking structure for fixing therewithin a portion of said blade when said blade is

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disengaged from said handle and said blade disengaging actuator is disengaged from said handle..." See, e.g. Claim 1.

Without an additional reference that teaches some sort of "hooking structure," the claims do not directly read on the Herbert reference, either alone or in combination with the other reference previously applied, viz. Newman et al. (US 2002/0143352).

After a further search, the examiner believes that Kiehne (US 6,629,985) teaches such a "hooking structure" designed to keep the blade inside the protective sheath when the blade is disengaged from the handle and the blade disengaging actuator is disengaged from the blade.

A large portion of Kiehne's disclosure is directed to keeping the blade inside the guard once the blade and guard are removed together from the handle for disposal.

Kiehne discloses,

"The assembly has a releasable attachment means. The releasable attachment means functions to initially attach the blade to the guard such that when the blade/guard assembly is removed from its protective package, the blade does not inadvertently fall out of the guard or expose a cutting edge. The attachment means can also function to hold the blade in the guard when the blade is removed for disposal. In one form, this can be achieved by a projection or button on the guard which extends into the slot in the blade body (the slot being where the handle attaches to the blade). The projection or button therefore prevents the blade from inadvertently sliding out of the guard and presenting a cutting edge.

"If desired, the guard may be provided with a further projection, or fin which extends into the slot in the blade and can function to prevent the blade from "rattling" in the guard."

Kiehne, col. 3, lines 48-63 (emphasis added).

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The structure of the fin is shown in, e.g., figure 12, where "the guard has an additional fin 31 which sits in slot 13 of blade 10 and functions to keep the blade central." See, col. 6, lines 41-43.

The question remains: can the fin 31 be considered a "hooking structure"? The American Heritage Dictionary defines "hook" as "A curved or sharply bent device, usually of metal, used to catch, drag, suspend, or fasten something else." "hook." The American Heritage® Dictionary of the English Language, Fourth Edition. Houghton Mifflin Company, 2004. 03 Oct. 2006. <Dictionary.com

http://dictionary.reference.com/browse/hook>

It is the examiner's contention that the fin 31 in Kiehne is a sharply bent device used for fastening something else, viz. the blade inside the guard.

As pointed out by Applicant, one disadvantage of the Herbert et al. reference is that one must continually press or engage the blade disengaging actuator to securely keep the blade within the guard. Kiehne overcomes this disadvantage by teaching, "As soon as [the blade is decoupled from finger 14], button 19, 50 [or, additionally fin 31] is released and [with the] bias of finger 20 will re-enter into slot 13 to again hold the blade within the guard. The blade and guard assembly can now be safely disposed of in a sharps bin with little or no likelihood of stick injury resulting." See, col. 5, lines 49-54.

Thus, to more securely keep the blade within the guard, it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify Herbert with the teachings of Kiehne.

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Further, the examiner does not believe the Kiehne reference teaches away from the Herbert reference because Herbert et al. disclose "The scalpel blade is selectively removed from engagement with the scalpel handle while the blade is still within the sheath. The scalpel blade is then retained in the sheath for further use or for safe and sanitary disposal of the blade within the sheath." See Herbert et al., col. 2, lines 44-48. Thus, both the Herbert and Kiehne references teach that it is advantageous to keep the blade within the sheath or guard for safe disposal, only Herbert et al. teach a less secure way of doing so.

The previous rejection to the claims along with reference to the above is as follows:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 25-27, 33-38, and 45 are rejected under 35 U.S.C. 103(a) as being anticipated by **Herbert**, U.S. Patent No. 5,868,771, in view of **Kiehne**, U.S. Patent No. 6,629,985. The patents to Herbert and Kiehne disclose a scalpel device.

Claim 1: Figure 1 of Herbert shows a blade 300 including an orifice 301. As to the "front and rear ends being disposed substantially in the same plane," Herbert discloses that only "[a] representative blade 300 is shown. The shape of the cutting edge of the blade and so forth are representative only. It is well known that there are

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many sizes, shapes, and styles of scalpel blades. The invention described herein is intended to cooperate with virtually any blade shape." Herbert, col. 4, lines 4-8. Herbert's figure 1 also shows a handle 100, a housing 200 configured to retain internally said blade and slide back and forth onto said handle. The housing includes a shoulder 202 (figure 10) that can be considered a sliding movement activator, and a blade disengaging actuator 217 on different sides of the housing 200. The actuator 217 is configured to disengage the blade 300 from the front handle portion.

In regard to the added limitations, see the discussion above. Again, to more securely keep the blade within the guard, it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify Herbert with the teachings of Kiehne.

Claim 25: The blade disengaging actuator 217 is adapted to flex at a first end (near 214). See Herbert, col. 5, line 13 (referring to the disengaging actuator flexing).

Claim **26**: The rear of the handle is adapted for hand grasping.

Claim **27**: The front handle portion is equipped with at least one groove 106 configured to fit into said blade orifice. See Herbert, figure 2.

Claim **33**: The blade disengaging actuator 217 is adapted at a second end (near 218B – figure 6) to push the internally retained blade toward the front handle portion which causes the blade to disengage from the front handle portion. As mentioned above, the flexing end is near 214 (<u>See</u> figure 6).

Claim **34**: The disengaged blade is retained internally by the housing for safety.

<u>See Herbert</u>, col. 5, lines 52-54.

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Claim **35**: The housing is decoupled from the handle by sliding the housing away from the groove on the front handle portion. <u>See Herbert</u>, col. 5, lines 37-58.

Claim **36**: The blade is retained internally by the housing via a plurality of integral blade retaining members 226, 227 ("ramps"). <u>See Herbert</u>, col. 6, lines 47-49.

Claim **37**: The plurality of integral blade retaining members includes at least two members adapted to frictionally retain the rear end of the blade within the housing. <u>See Herbert</u>, col. 6, lines 47-49.

Claim **38**: See rejection above under 35 U.S.C. 112. The plurality of integral blade retaining members frictionally engage the blade to retain the housing portion with the groove in the orifice.

Claim **45**: Herbert discloses that the blade is completely enclosed by the housing for safety when the housing is decoupled from the handle portion. <u>See Herbert</u>, col. 5, lines 37-58.

Claims 29-32, and 40-44 and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Herbert** and **Kiehne** as applied to claim 27 above, in view of **Newman et al.**, **U.S. 2002/0143352** (hereinafter "**Newman**").

Claims 29-32, 40: Herbert does not disclose a guide channel in the handle to guide the housing. However, Newman discloses a guide channel 21 that can be said to be flanked by a "locking bar," i.e., the handle material above the guide channel 21. The housing in Newman is adapted to slide within this guide channel 21 when activated (claim 30). Herbert discloses a sliding movement activator 41 that includes a stop 42 member at a first end 21a, said stop member being adapted to lock said housing at

opposite ends (21a and 21b) of said locking bar. The stop member is further adapted to unlock the housing and slide within a guide channel 21 when the sliding movement activator 41 is pressed toward the locking bar. The sliding movement activator 41 is adapted to flex at a second end 21b, said second flexing end being disposed substantially opposite said stop member 21a at said first end. See Newman, figures 4-6.

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It would have been obvious to one of ordinary skill in the art at the time of the invention to combine these references because they involve the same field of endeavor (shielded surgical scalpels), and providing a guide channel and a stop member on the handle portion in Herbert, as disclosed by Newman, would add stability and safety to the scalpel assembly, respectively.

Again, to more securely keep the blade within the guard, it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify Herbert with the teachings of Kiehne.

Regarding claims 41 and 46-48, Herbert does not disclose a stabilizing rail. However, Newman discloses a stabilizing rail 42 adapted to slide back and forth in the guide channel 21 of the first handle portion between a first position 21b in which the surgical blade is exposed for operational use and a second position 21a in which the surgical blade is fully enclosed within the housing for safety, said surgical blade being securely engaged by the first handle portion in the first and second positions.

In addition to the limitations described above (i.e. a blade, handle, housing), Herbert discloses a blade disengaging actuator 217 that when combined with Newman. would be configured to operate independently of the sliding movement activator, said sliding movement activator 41 and said blade disengaging actuator 217 being hinged respectively to adjacent sides of the housing, when the two references are so combined.

It would be obvious to combine Herbert and Newman because they involve the same field of endeavor (shielding surgical scalpels) and providing a stabilizing rail allows the blade to stay in a proper orientation when being moved forward and backwards.

Regarding claim **42**, the hinged actuator 217 disclosed by Herbert is configured to disengage the surgical blade from the first handle portion when the housing is in the second position. <u>See Herbert</u>, col. 5, lines 37-58.

Regarding claim **43**, Newman's figure 1 shows that the blade has a front cutting end, a rear end, and an orifice 31, where the first and second ends are disposed in substantially the same plane.

Regarding claim **44**, as mentioned above, Herbert discloses that the blade is completely enclosed by the housing for safety when the housing is decoupled from the handle portion. <u>See Herbert</u>, col. 5, lines 37-58.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Thomas Andersen whose telephone number is (571) 272-8024. The examiner can normally be reached on M-F 8AM-4:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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M. Thomas Andersen

October 3, 2006

MICHAEL J. HAYES SUPERVISORY PATENT EXAMINER